



SUBJECT: Documentation of Informed Consent/
Parental Permission and Assent

POLICY: RA:HRPP:07.03

DATE EFFECTIVE:

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I. POLICY

In accordance with federal regulations, Informed Consent/Parental Permission to participate in human subjects research must be documented in writing. The Children's National Medical Center (CNMC) Institutional Review Board (IRB) also requires documentation of assent by children and adolescents ages 7 through 17.

Oral agreement to participate in a research study is NOT permitted unless the documentation or process of informed consent is waived by the IRB. Additional information regarding waivers can be found in RA:HRPP:07.04 and 07.04P, *Waivers and Alterations of Informed Consent/Parental Permission*.

Informed consent must be obtained in a language that is understandable to the subject. When an investigator anticipates enrolling non-English-speaking subjects, the protocol must reflect the methods for assuring full understanding.

II. ACCOUNTABLE EXECUTIVE AND REVIEWER(S)

- A. Accountable Executive: Chief Academic Officer/Institutional Official for the Federalwide Assurance
- B. Department Responsible for Review: Office for the Protection of Human Subjects
- C. Committee Responsible for Review: Institutional Review Board Executive Committee
Research Policy/Procedure Working Group

III. APPROVAL

Approved by:

IRB Executive Committee

11/12/2009

Date

Research Policy/Procedure Working Group

Date

Mark L. Batshaw, M.D., Chief Academic Officer

Date

IV. APPLICABILITY

Areas where the policy and procedure applies: Children's Research Institute, Children's National Medical Center

Persons to whom the policy and procedure applies: Investigators, research staff, Institutional Review Board, Office for the Protection of Human Subjects

V. REVIEW OR REVISION DATE

Original:

VI. REFERENCES

AAHRPP Elements:

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.117

Food and Drug Administration (FDA) 21 CFR 50.27

Policies and Procedures: RA:HRPP:07.04 and 07.04P, *Waivers and Alterations of Informed Consent/Parental Permission*

Forms: Consent to Participate in a Clinical Research Study and Authorization to Use Protected Health Information (template),
Consent to Participate in a Clinical Research Study (template),
Assent (Ages 12 through 17) to Participate in a Clinical Research Study (template),
Assent (Ages 7 through 11) to Participate in a Clinical Research Study (template),
Instructions for Using "Short Form" Consent Documentation,
Informed Consent Document – Short Form,
Documento de Consentimiento Informado - Formulario Corto

SUBJECT: Documentation of Informed Consent/
Parental Permission and Assent

PROCEDURE: RA:HRPP:07.03P

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I. PROCEDURE

A. Overview

1. Informed Consent/Parental Permission and Assent by children and adolescents ages 7 through 17 must be documented in writing as determined in the Institutional Review Board (IRB) review and approval process.
2. There are two options for documentation of Informed Consent/Parental Permission and Assent:
 - a) A written consent/permission and assent form signed by the subject, parent, or legally authorized representative; or
 - b) A short form written consent with oral presentation.
3. It is the responsibility of the IRB to determine which of these options is appropriate for documenting informed consent in research applications that it reviews. Generally, only a signed written document will be appropriate. This method is described further in the current procedure, as is short form written consent with oral presentation.
4. There are circumstances in which the IRB may grant a waiver of documentation of informed consent or permission in accordance with Federal regulations. They are described in RA:HRPP:07.02 and 07.02P, *Informed Consent/Parental Permission and Assent Process*.

B. General Requirements

1. Parents and guardians are asked to document their permission to allow their children to participate in research by signing an Informed Consent/Parental Permission Form. The consent/permission of both parents is required unless the determination has been made that the consent of one parent is sufficient. The IRB will advise investigators as to whether the signature of one or both parents is required.
2. Informed consent must be documented on a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A signed copy is to be given to the person signing the form. Unless otherwise approved by the IRB, another copy of the signed consent form is to be placed in the medical record, if the study involves medical interventions, to ensure the safety of the patients who participate in research.

Informed consent must be obtained before the initiation of any screening procedures performed solely for the purpose of research.

3. The person obtaining consent (study investigator or designee) is also required to sign the consent document to attest to the fact that all the elements of informed consent have been explained to the subject/legally authorized representative (parent/guardian) and all questions have been answered to the best of the investigator's ability.

C. Writing the Consent/Parental Permission and Assent Documents

1. Investigators are to use the templates available on the IRB/Office for the Protection of Human Subjects (OPHS) intranet site when writing consent/parental permission and assent documents for their studies.
2. The investigator is responsible for incorporating the required basic and additional elements of informed consent into the informed consent documents, as required by Federal Regulations and determined by the Institutional Review Board (RA:HRPP:07.01 and 07.01P, *Elements of Informed Consent*).
3. The information provided in the informed consent documents must be in language understandable to the subject (target population). The informed consent documents should not include complex language that would not be understandable to all subjects.
 - a) Technical and scientific terms should be adequately explained using common or lay terminology consistently. Generic names are preferable when describing pharmaceuticals unless the brand name is more commonly known and understood. Regardless of which name is preferred, it should be used consistently throughout the informed consent documents. Devices and procedures should also be described consistently throughout the documents and explained in simple language.
 - b) It is generally recommended that the adult consent/parental permission documents be written at approximately a seventh grade reading level. All assent forms must be written in a way that is simple and easy to understand.
 - c) To assist investigators, the IRB/OPHS intranet site has links to specialized glossaries that provide lay terms for common medical conditions and procedures.
4. No informed consent, whether oral or written, may include exculpatory language whereby a subject or representative is made to waive or appear to waive any of his or her rights, or to release or appear to release the investigator, sponsor, institution, or its agents from liability or negligence.
 - a) Examples of Acceptable Language:
 - i. Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

- ii. By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above. You understand that you will not receive any financial compensation.

b) Examples of Unacceptable Exculpatory Language:

- i. By agreeing to this use, you should understand that you would give up all claims to personal benefit from commercial or other use of these substances.
 - ii. I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
 - iii. By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
 - iv. I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.
5. No unproven claims of effectiveness or certainty of benefit, either implicit or explicit, may be included in the informed consent documents.
 6. Any changes in the informed consent documents must be submitted as a modification to the IRB for review and approval prior to implementation.

D. Signature of Subject or Legally Authorized Representative

1. The IRB requires the signature of the subject or legally authorized representatives (parents/guardians) on informed consent/parental permission documents unless a waiver or alteration of consent is approved. During the review process, the IRB determines the signatures required and incorporates these requirements in the final approved consent/parental permission forms.
2. The consent/permission of both parents is required unless the determination has been made that the consent of one parent is sufficient.
 - a) Where parental permission is to be obtained, both parents must give their permission for research to be conducted under the following circumstances:
 - i. The research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406, 21 CFR 50.53);
 - ii. The research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407, 21 CFR 50.54). (This category of research requires a special review and determination by the Secretary of the Department of Health and Human Services or the Commissioner of the Food and Drug Administration before a study can be implemented.)

- b) Exception to the requirement for both parents' signatures occurs when one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
 3. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under the following circumstances:
 - a) The research does not involve greater than minimal risk (45 CFR 46.404, 21 CFR 50.51);
 - b) The research involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects (45 CFR 46.405, 21 CFR 50.52).
 4. All consent documents must contain the date signed by the subject, the subject's parents/guardians or the subject's legally authorized representative (RA:HRPP:07.02, 07.02P).
 5. In situations involving the variety of legally recognized arrangements that exist, refer to RA:HRPP 07.02 and 07.02P. Some of these situations include those that involve custody of children, guardians for children, wards, and children in foster home situations. However, not all guardians have the legal right to consent to research for a child. In many instances, biological parents maintain this right. Moreover, differences exist in consent procedures related to clinical care versus research. For these reasons it is important that investigators contact the Office for the Protection of Human Subjects or the CNMC Legal Department if questions arise as to who constitutes a legally authorized representative for a child.
 6. If the IRB reviews research that is conducted in another state or country, the determination as to who may sign the consent and who is a legally authorized representative must be determined by the locality where the research takes place.
- E. Assent from the Child/Adolescent
 1. The CNMC IRB requires a separate assent process that is to be documented for children and adolescents. Assent by children ages 7-11 years must be documented using an Affidavit of Person Obtaining Assent added to the parental permission form. For 12-17 year-old subjects, assent is to be documented by obtaining subjects' signatures on a separate form. Assent forms must follow the Children's National Assent Form template and be written in a way that is understandable by the 12-17 age group.
 2. The IRB is to determine whether adequate provisions are made for soliciting the assent of a child or adolescent when, in the judgment of the IRB, the child/adolescent is capable of providing assent. See RA:HRPP:07.02 and 07.02P for guidance when assent need not be obtained.

3. As part of the IRB application and review process:
 - a) The investigator is to indicate on the protocol application his or her initial determination as to whether assent may be obtained.
 - b) During the review process, the IRB is to review the investigator's justification and determine whether assent is required.
 - c) The investigator is to be advised in the approval notification whether assent is required.
 - d) The IRB meeting minutes are to document the committee's determination.

F. Signature of Individual Obtaining Informed Consent/Parental Permission/Assent

1. The signature of the individual responsible for obtaining informed consent must be included on all consent documents, along with the date of the signature.
2. Individuals other than the investigator may obtain consent; however, any individual who obtains consent must be listed on the protocol application as having this role.
3. It is the investigator's responsibility to train, oversee, and monitor all individuals who obtain consent on his or her protocol.
4. The individual who obtains consent is not required to be present to witness the subject/parent sign the consent.
5. Only after a subject signs the consent is the individual who obtained consent to sign the document. The signature of the person who obtains consent is not to be "back dated" to coincide with the date of the research subject's signature.

G. Witness Signature

1. A witness signature is required only in the following circumstances:
 - a) If the IRB approves the use of the "short form" (see section I.2 below);
 - b) When the subject cannot read and the consent document must be read to him or her;
 - c) When communication impairments limit a subject's ability to unambiguously register consent. In such cases, it is important that there be an independent observer of the communication;
 - d) When, given the nature of the research and the anticipated condition of a subject, the IRB is concerned that questions may arise as to whether consent/assent is being given knowingly and voluntarily. In these situations, verification of the consent may help to protect subjects, who may be temporarily sick or too upset to provide meaningful consent/assent under the anticipated circumstances.

2. The witness must be present during the oral presentation of the consent. His or her signature confirms that the information in the consent form and other written documents was accurately explained to, and ostensibly understood by, the subject or the subject's legally authorized representative, and that the informed consent was given freely.

H. Obtaining Consent/Parental Permission if Parent/Guardian is Not Present

1. Federal regulatory agencies do not regard verbal telephone consent as meeting the documentation of informed consent requirements of the federal regulations. Although verbal telephone consent is accepted and frequently obtained for clinical care, this practice does not automatically apply to consent for research protocols. The guidelines below are provided to assist investigators in obtaining informed consent when a parent/guardian is not present to sign the informed consent/parental permission document within a reasonable time frame specified by a research protocol.
2. Guidelines for obtaining informed consent/parental permission for an approved research protocol when the parent/guardian is not present with the subject are as follows:
 - a) All reasonable efforts must be made to obtain written informed consent from the parents/guardians of eligible children prior to study enrollment.
 - b) If a parent is present at the hospital or will be present within the time frame for recruitment, the IRB-approved informed consent must be signed prior to enrollment.
 - c) If a parent is nearby, investigators have the option to speak with the parent by phone and send an appropriate designated individual to the parent to obtain written consent. Alternatively, the investigator may speak with the parent/guardian by phone, and fax or send by messenger a copy of the consent to the parent/guardian for signature. When the parent/guardian receives the consent form it must immediately be signed and sent/faxed back to the investigator. Only after the investigator receives the signed consent may the patient may be enrolled.
3. **Verbal phone consent/parental permission alone is prohibited, unless the IRB approves a waiver of documentation of informed consent.** (See RA:HRPP:07.04 and 07.04P, *Waivers and Alterations of Informed Consent/Parental Permission*) **Investigators and research staff shall not enroll a child relying on phone consent/permission from the parent/guardian.**

- a) The research design of certain studies (e.g., telephone surveys) may entail a process for obtaining informed consent/assent by telephone and through the mail, with the justification that this method is appropriate when face-to-face contact with subjects and parents/guardians is neither necessary for the study nor practicable. See RA:HRPP:07.05 and 07.05P, *Obtaining Informed Consent/Parental Permission and Assent via Telephone and Mail*.

I. Informed Consent in Other Languages

1. Translated Informed Consent Documents

- a) The IRB prohibits the exclusion of non-English speaking individuals from research protocols unless there is a sufficient justification for the exclusion. In particular, if a research protocol offers a potential for direct benefit that may only be available within the context of the research, the exclusion of non-English speaking individuals becomes ethically problematic. Investigators are obliged to consider the potential that study populations may include non-English speaking individuals and to plan for this while developing the protocol.
- b) Informed consent must be obtained in a language that is understandable to the subject. When an investigator anticipates enrolling non-English-speaking subjects, the protocol must reflect the methods for assuring full understanding, typically with the assistance of an interpreter and by using translated informed consent documents.
- c) If the investigator intends to use a translated version of the informed consent document(s), the IRB must review and approve the translated version(s) prior to use. The credentials of the person who did the translation must be provided to the IRB, along with a statement from the translator that the foreign language consent document(s) is (are) an accurate translation of the English version.
- d) Investigators also may be required to translate other study documents to assure subjects' full understanding throughout their participation. Likewise, an interpreter may be required, not only during the informed consent process, but also for ongoing interactions with the subject.
- e) Justifications for excluding non-English speaking subjects usually include scientific and methodological limitations based on the lack of appropriate validated instruments, surveys or assessments. In some situations use of another language may confound the research results or not permit appropriate analysis of the data, especially when protocols are designed with a small sample size. These concerns are usually limited to behavioral and social research.
- f) It is an investigator's obligation to determine whether there are appropriate alternate assessments, instruments, or surveys that could be utilized for non-English speaking subjects prior to excluding them.
- g) In order to ensure the inclusion of non-English speaking individuals in research, the following guidelines are provided.
 - i. Corporate Sponsored Research: When research is sponsored by a corporate entity, the clinical trial agreement negotiated between the company and CNMC should include a provision

for the sponsor to cover the costs of translating consents and other important research documents. This cost could be included as a line item within a budget or, if there is uncertainty as to whether non-English speakers will be eligible, it may be included as a provision, if needed, in the agreement.

- ii. Federally Funded Research: When research is federally funded it is permissible to include the translation of research documents and the potential use of an interpreter as direct expense in a budget. Investigators should include these costs in their budgets.
- iii. Language Services: The CNMC Department of Family Services has a Language Services program that is available to assist researchers with (oral) interpretation of a number of foreign languages when recruiting and interacting with a non-English speaking individual. Sign language interpretation services are also available. Investigators should contact Language Services as soon as they anticipate a need for an interpreter. This will permit planning for appropriate staffing. While a translator may be helpful in facilitating conversations with non-English speaking families, ad hoc verbal translation of the consent document should not be substituted for written translation when recruitment of non-English speaking individuals is anticipated. It is preferable that the subject and his/her family be given documents that they can take with them in their language. Language Services can facilitate the (written) translation of consent/assent documents and research materials through a contract agency. Contact Language Services for more information.

2. “Short Form” Informed Consent Documents

- a) If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on oral interpretation. Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective.
- b) Federal regulations permit informed consent to be documented using a “short form.” The short form states that the elements of informed consent required by the regulations have been presented orally to the subject or the subject's legally authorized representative. It does not include specific study descriptions; rather, it lists the elements of informed consent such as purpose, procedures, risks, benefits, etc., that have been explained to the subject/parent.
- c) If an investigator wants to enroll a non-English speaking subject without an IRB-approved written translation of the full consent form, he or she should use one of the IRB-approved "short form" written consent documents when applicable. These can be found on the OPHS/IRB intranet site in English, Spanish, and several other

languages common among patients served by CNMC). If the available short form translations do not include the subject’s language, the investigator must have the short form translated into the appropriate language and submit it to the IRB for approval prior to its use.

- c) The IRB must approve a written summary of what is to be said to non-English speaking subjects during the consenting process when a short form is used. If the standard IRB-approved Informed Consent Document is presented orally through a translator, it serves as the summary.
- d) The short form must be signed and dated by the subject or the representative to document informed consent.
- e) When the short form method of documenting consent is used, there must be a witness to the oral presentation who is fluent in both English and the subject’s language. The witness must also sign and date the short form and a copy of the full informed consent document, and attest that the information in the consent form and other written documents was presented in a language understandable to the subject/parent, the subject/parent had the opportunity to ask questions, and informed consent was given freely.
- f) The investigator or IRB-approved designee who obtains consent must sign and date the full (English) informed consent document. Copies of both the full informed consent document and the short form must be given to the subject or the representative, and the originals are to be placed in the subject’s research file.

Signature Requirements When Using the Short Form Consent Document		
Signatory	Full Consent Form	Short Form Consent
Subject or representative	No	Yes
Person obtaining consent	Yes	No
Witness	Yes	Yes

J. Illiterate Subjects

- 1. Every investigator is responsible, under the informed consent process, for ensuring that potential research subjects/parents are capable of reading an informed consent/parental permission form before asking them to review and sign one. (Children under a certain age are presumed to be unable to read; this policy is not intended for this population.) Investigators are not to assume that subjects/parents are able to read and, when appropriate, are to inquire in a sensitive way as to whether the subjects/parents are able to do so.
- 2. If the potential subjects/parents cannot read the informed consent form, investigators are to make special arrangements without causing embarrassment to the subjects/parents. Illiterate subjects are not to be excluded from the research because they are unable to read unless there is an overriding scientific or safety concern.

3. The following IRB recommendations are to be implemented if, when asked to provide permission, a research subject or parent/guardian is determined to be illiterate:
 - a) If illiterate (in whatever the language of the consent process) but cognitively competent, the consent process proceeds as usual. The informed consent is to be read to the subject/parent, and the subject/parent is to be encouraged to ask questions.
 - b) The consent process must be conducted with a witness present. In this case, the witness is to observe the entire process, not just the signature.
 - c) The generic “short form” should be used to document that all of the required elements of informed consent were explained to the subject/parent. If able, the subject/parent is to affix a signature to or make an "X" on the short form consent document.
 - d) The witness is to sign and date both the full consent document and the short form to attest, in writing, that the process took place, the subject/parent had the opportunity to ask questions, and that the subject/parent voluntarily consents to participate. (For further information about the use of short forms see RA:HRPP:07.06 and 07.06P, “*Use of Short Forms for Documenting Informed Consent.*”)

K. Institutional Review Board Submissions

1. Investigators must include all consent/parental permission and assent documents in their initial and continuing review IRB submissions and with modification requests if the modification makes changes to those documents necessary.
2. The IRB Regulatory Analyst assigned to the study will conduct a pre-review of the entire submission and make an initial determination whether:
 - a) The information included in the consent/parental permission and assent documents meets the Federal regulatory criteria and general IRB requirements; and
 - b) The information in the consent/parental permission and assent documents matches the description of the protocol in the IRB application documents.
3. The Analyst will use track changes to indicate any issues he/she finds with the submitted documents. Next, the Analyst will forward the transaction for review by the IRB Chair or his designee. Once the Chair (or designee) has completed his review, the Analyst will send their collective change requests to the investigator. If the transaction requires full board review, the results of the Analyst and Chair’s pre-review and the investigator’s responses will be included among the materials reviewed and discussed at the convened meeting.
4. The assigned reviewer(s) is (are) responsible for conducting a complete review of the protocol submission and for verifying that the basic elements and applicable additional elements of informed consent are present in the

consent/parental permission documents in accordance with Federal regulations and IRB requirements. Consent documents that contain excessive scientific or medical jargon will be returned to the investigator for revision with recommendations to simplify the language. The reviewer(s) may request necessary revisions to the content, language, punctuation, and/or grammar of the consent and assent documents in order for the intended target population to clearly understand the proposed research activities and make an informed decision on whether to participate in the research.

5. The reviewer(s) is (are) required to use the Reviewer Feedback Form to document his or her determinations. For studies requiring review at a convened meeting of the IRB, the committee is to consider the consent/assent documents when makes its approval determination.

II. REVIEW OR REVISION DATE

Original:

Revised: May 1, 2012

III. REFERENCES

AAHRPP Element(s):

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.404-408
Food and Drug Administration (FDA) 21 CFR 50.20, 56.111(a)(4)

Policies and Procedures: RA:HRPP:07.01 and 07.01P, *Elements of Informed Consent*
RA:HRPP:07.02 and 07.02P, *Informed Consent/Parental Permission and Assent Process*
RA:HRPP:07.04 and 07.04P, *Waivers and Alterations of Informed Consent/Parental Permission*
RA:HRPP:07.05 and 07.05P, *Obtaining Informed Consent/Parental Permission and Assent via Telephone and Mail*

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